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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,830	05/30/2001	Volker Lehmann	00 P 21957 US	6111

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EXAMINER

GORDON, BRIAN R

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/867,830

Applicant(s)

LEHMANN, VOLKER

Examiner

Brian R. Gordon

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7-5-05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings were received on July 05, 2005. These drawings are acceptable.

Specification

2. The abstract of the disclosure is objected to because the specifications employs the used of reference numbers [1], [2], and [3] within the text of the specification to refer to the citations of the bibliography. This is generally not accepted as a proper format for a patent application. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2 and 6-10 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The particular structure of the Flow-Thru Chip ® critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant discloses the invention as incorporating the structure of the Flow-Thru Chip ® only, however it is not clear what is the required structure of the chip. Applicant has not provided a patent number for one to rely upon as a description of the structure of the analysis chip intended to be used within the claimed device. The term "analysis chip" may be used to characterize a number of devices; however, applicant has

disclosed the invention as functioning only with the above named chip. Applicant is hereby required to present an incorporation of a patent number. The non-patent literature provided may not be incorporated by reference. Therefore considered insufficient for providing a detailed description of the trademarked chip employed by applicant.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 7, 8, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and 7 read as "a plurality of wells for taking up aspirating an analyte", this implies the wells are used to aspirate an analyte. However, it is the pipettes which aspirate the analyte.

Claim 8 is references a diaphragm however the device is described as having two diaphragms (207 and 406). The claim should clearly specify which diaphragm is being claimed.

Claim 10 is directed to a process limitation or the intended use of the pump. The examiner suggests canceling the claim for a process limitation adds no patentable weight to an apparatus. Furthermore, the function is claimed in a way that implies the pump would be inoperable as intended be used. It is well known in the art that in order for a liquid to be aspirated a pressure that is greater than the force of the surface tension of the liquid must be applied. If not, the liquid will not move.

Examiner Comments

3. In an effort to expedite the prosecution of the instant application, on July 25, 2005, 2005 the examiner placed a call to Jeffrey Stone. The examiner informed Mr. Stone of the existing 112, second paragraph issues and presented applicant with a proposed claim to remedy the claim of those issues and further clarify the claim with other minor changes. Applicant did not approve the changes and requested an office action. The examiner recognizes applicant's cooperation with making the previous suggested changes. However, after further review further errors were found. The proposed changes are given below. In claim 1, several commas were removed and replaced with semi-colons.

1. (Currently amended): An apparatus for aspirating and dispensing liquid analytes, comprising a microtitre plate with a plurality of wells holding for aspirating an analyte therein; a plurality of pipettes corresponding with each well; by which an analyte can be withdrawn from said corresponding wells if the pipettes are immersed into the analyte of the corresponding wells, at least one pump, which is coupled to a plurality of said pipettes in such a way that an analyte in each well is transferred through a corresponding pipette by means of the ~~pump, and pump~~; wherein analytes can be simultaneously aspirated out of a plurality of said wells or introduced into a plurality of said wells by actuating the pump, the apparatus further comprising a plurality of analysis chips arranged in an intermediate plate for analyzing the analyte and a plurality of corresponding chambers, wherein said analysis chips correspond respectively with each well in order to analyze an analyte introduced into each respective well; wherein each analysis chip comprises a plurality of liquid channels; wherein each analysis chip is arranged between a respective chamber in ~~the~~ a flow path of the analyte from a well into a pipette and into a chamber or from a chamber into a pipette and into a well; wherein the analyte is transferred through the liquid channels of the analysis chip into a chamber or out of a chamber, respectively, and wherein a portion of a surface area of the liquid channels of the analysis chips comes into contact with the analyte, said surface area is constructed to allow biological material for binding molecules contained in the analyte to be fixed thereon.

In dependent claim 2, line 3 amend the phrase "an intermediate plate" to "an the intermediate plate"

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In dependent claim 2, lines 4-5 delete the phrase “, and wherein the analysis chips are arranged in the intermediate plate”

Amend claim 6 as follows”

6. (currently amended): The apparatus according to Claim 1, wherein the portion of the surface ~~the surface of at least a part of the surface of the liquid channels of the analysis chips, which surface of at least a part of the liquid channels of the analysis chips~~ that comes into contact with the analyte, has further comprises biological material for binding the molecules contained in the analyte.

In claim 7, lines 2-3, delete “for taking up aspirating an analyte”

In claim 8, line 2 delete “elastic diaphragm” and insert the following --elastic, pump-diaphragm--

Delete claim 10.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 6-8, 10 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenny US 4,461,328 in view of Kopaciewicz et al US 6,830,717.

Kenney discloses a pipette device comprises one or more pipette tubes. The device can be adapted to be connected to a manifold for alternately applying a vacuum and pressure to the pipette tubes. The pipette device 2 in accordance with the invention has a pipette tray 3 with a plurality of conically shaped pipette tubes 4 adapted to register with wells 6, for example, culture wells, in a conventional well tray 8. The upper end of each tube 4 is integral with a substantially rigid plate 12 which has an upstanding peripheral flange 14.

Kenney does don't disclose each pipette tube as comprising an analysis chip.

Kopaciewicz et al. discloses composite structures comprising particles entrapped within a porous polymeric substrate, and are cast in-place into a housing such as a pipette tip, thereby providing an effective platform for micromass handling. With the appropriate selection of particle chemistry, virtually any separation or purification operation can be conducted, including selective bind/elute chromatography operations, on sample mass loads less than 1 microgram in volumes of a few microliters, as well as larger mass loads' and volumes.

Devices in accordance with the present invention may incorporate a plurality of composite structures having resin materials with different functional groups to fractionate analytes that vary by charge, size, affinity and/or hydrophobicity; alternately, a plurality of devices containing different individual functional membranes may be used in combination to achieve a similar result.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kenney by employing the membranes (analysis chip) as taught by Kopaciewicz within the tips in order to fractionate various analytes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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